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EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,172	FUENTES ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The election **without traverse** filed September 24, 2009, is acknowledged and has been entered.

Applicant has elected the invention of Group I, drawn to a pharmaceutical combination for the treatment of neoplasia through simultaneous, separate, or sequential administration, comprising GnRH, or its analogues coupled or not to an immunopotentiating carrier protein and natural or recombinant EGF or its mutated variants, or derivative peptides, or EGF mimetic peptides, or EGF analogues, coupled or not to an immunopotentiating carrier protein.

2. The amendment filed September 24, 2009, is acknowledged and has been entered. Claims 1 and 3 have been amended.

3. Claims 1-8 are pending in the application.

4. Claim 7-8 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species of election, there being no allowable generic or linking claim. Applicant elected without traverse in the reply filed September 24, 2009.

5. Claims 1-6 are under examination.

Response to Amendment

6. The amendment filed on September 24, 2009, is considered non-compliant because it fails to meet the requirements of 37 C.F.R. § 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003). However, in order to advance prosecution, rather than mailing a Notice of Non-Compliant Amendment, Applicant is advised to correct the following deficiencies in replying to this Office action:

The amendment to the claims is non-compliant because the status identifiers of

claims 2 and 4-8, which appear in parentheses, improperly indicate that the claims have been amended.

In this case, while the format of the number of the claim has been modified in the amendment, the text of the actual claim has not been amended as set forth in 37 C.F.R. § 1.121. Accordingly, the claim has not been amended and the status identifier "currently amended" is incorrect.

Applicant is reminded: Only the corrected section(s) of the non-compliant amendment must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment must be re-submitted. 37 C.F.R. § 1.121(h).

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

In this case, while the declaration pages contain page numbers none of the pages indicate that there are any additional declaration pages attached to them. Therefore it cannot be known whether the declaration signed by each inventor contained a complete listing of all inventors. While each inventor need not execute the same oath or declaration, each oath or declaration executed by an inventor must contain a complete listing of all inventors so as to clearly indicate what each inventor believes to be the appropriate inventive entity. Where individual declarations are executed, they must be submitted as individual declarations rather than combined into one declaration. For example, where the inventive entity is A and B, a declaration may not be executed only by A naming only A as the inventor and a different declaration may not be executed only by B naming only B as the inventor, which two declarations are then combined into one declaration with a first page of boiler plate, a second page with A's signature, and a second page with B's signature (so that it appears that the declaration was executed with the entire inventive entity appearing in the declaration when it did not). In this case, while the inventors listed on page 6 would know that there

should be 5 preceding pages, the inventors listed on earlier pages would not be apprised of the total number of pages contained in the declaration since the declaration only provides a page number on each page without indicating the total number of pages which makes up the declaration and it cannot be known whether the declaration signed by each inventor contained a complete listing of all inventors.

Accordingly a new oath or declaration in compliance with 37 CFR 1.63 including the entire inventive entity is required. See MPEP 201.03, 605.04 and 37 CFR 1.63.

Information Disclosure Statement

8. The references cited in the information disclosure statement filed on September 14, 2005, have been considered.

Claim Objections

9. Claims 1-6 are objected to as being drawn to the subject matter of non-elected inventions; i.e., the claims are directed in the alternative to the subject matter of the non-elected inventions of Group II-LXXXVIII.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In this case, the claims are drawn to a pharmaceutical "***combination***" for the treatment of neoplasia through simultaneous, separate, or sequential administration, comprising GnRH, or its analogues coupled or not to an immunopotentiating carrier protein and natural or recombinant EGF or its mutated variants, or derivative peptides, or EGF mimetic peptides, or EGF analogues, coupled or not to an immunopotentiating

carrier protein.

Notably, 35 U.S.C. 101 sets forth that the invention or discovery of *a* "composition of matter", i.e., a single "composition of matter", is patentable, but the instant claims are instead drawn to a "combination" of two seemingly different and independent compositions, one composition which contains GnRH and the other composition which contains EGF, and which are not present in a single composition of matter. As set forth in claim 1, the two compounds are to be administered simultaneously, separately or sequentially which evidences that the claims are not drawn to a single composition of matter, but to two different compositions which are separate from each other since a single composition of matter comprising two components cannot be used to administer the two components separately.

In this case, it is submitted that the claimed subject matter is analogous to a claim reciting "an apple and an orange for simultaneous, separate, or sequential consumption". Just as the apple and orange are separate from each other in this example, so are the two independent compositions, one containing GnRH and the other containing EGF, as instantly recited. Furthermore, just as apples and oranges are known separately in the art, so are the two independent compositions, i.e., US Patent 5,211,952 (Spicer et al, 1993) discloses compositions comprising GnRH (see entire document, e.g., abstract), while US Patent 5,894,018 (Gandolf et al, 1999, IDS filed 9/14/09) discloses compositions comprising EGF (see entire document, e.g., abstract). Accordingly, it is apparent that the claims recite two separate compositions of matter and not to a single composition of matter as required by 35 USC § 101.

For these reasons, it is submitted that the claims are drawn to non-statutory subject matter.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 3 is indefinite for reciting "the GnRH analogue peptide". Notably, while independent claim 1 recites GnRH analogues, it does not refer to any GnRH analogue peptide, so the recitation "the GnRH analogue peptide" lacks antecedent basis and it cannot be determined which (if any) GnRH analogue peptide is being referred to in claim 3. Accordingly, this claim fails to delineate the metes and bounds of the invention with the clarity and particularity necessary to satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph, so as permit the skilled artisan to know or determine infringing subject matter.

(b) Claim 6 is indefinite for reciting "the conjugated chimeric protein". In this case, independent claim 1does not refer to any conjugated chimeric protein, so the recitation "the conjugated chimeric protein" lacks antecedent basis and it cannot be determined which (if any) conjugated chimeric protein is being referred to in claim 6. Accordingly, this claim fails to delineate the metes and bounds of the invention with the clarity and particularity necessary to satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph, so as permit the skilled artisan to know or determine infringing subject matter.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description'' Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereinafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

Furthermore, the Federal Circuit has commented that each case involving the issue of written description, "must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited." *Vas-Cath*, 935 F.2d at 1562 (quoting *In re Driscoll*, 562 F.2d 1245, 1250 (C.C.P.A. 1977)). See *Noelle v. Lederman*, 69 USPQ2d 1508 (CAFC 2004).

Finally, with further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained

that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention.*

In the instant case, claims 1-6 recite a structurally and functionally diverse genus of "GnRH analogues" or structurally and functionally diverse genera of "EGF mutated variants", "EGF derivative peptides", "EGF mimetic peptides" or "EGF analogues".

Notably, the claims do not require that the recited "GnRH analogues", "EGF mutated variants", "EGF derivative peptides", "EGF mimetic peptides" or "EGF analogues" to have any structure or function and therefore, there can be no correlation of any particular identifying structural feature with any function of the recited proteins. Furthermore, it is noted that the specification does not adequately describe the recited "GnRH analogues", "EGF mutated variants", "EGF derivative peptides", "EGF mimetic peptides" or "EGF analogues" as having any particularly identifying structural feature which would allow one of skill in the art to immediately envision or recognize a member of any of the respective genera from any other.

"[G]eneralized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). Here, there is no language that adequately describes the genera of

"GnRH analogues", "EGF mutated variants", "EGF derivative peptides", "EGF mimetic peptides" or "EGF analogues" to which the claims are directed.

Given the lack of particularity with which the "GnRH analogues", "EGF mutated variants", "EGF derivative peptides", "EGF mimetic peptides" or "EGF analogues" to which the claims are directed, are described in the specification, it is submitted that the skilled artisan could not immediately envision, recognize or distinguish at least most of the members of the genera of "GnRH analogues", "EGF mutated variants", "EGF derivative peptides", "EGF mimetic peptides" or "EGF analogues" to which the claims are directed; and therefore the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
December 29, 2009